

§ 1311.115

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institutional practitioner (e.g., a hospital credentialing office) may conduct identity proofing and authorize the issuance of the authentication credential. That entity must do the following:

(1) Ensure that photographic identification issued by the Federal Government or a State government matches the person presenting the identification.

(2) Ensure that the individual practitioner's State authorization to practice and, where applicable, State authorization to prescribe controlled substances, is current and in good standing.

(3) Either ensure that the individual practitioner's DEA registration is current and in good standing or ensure that the institutional practitioner has granted the individual practitioner exempt from the requirement of registration under § 1301.22 of this chapter privileges to prescribe controlled substances using the institutional practitioner's DEA registration number.

(4) If the individual practitioner is an employee of a health care facility that is operated by the Department of Veterans Affairs, confirm that the individual practitioner has been duly appointed to practice at that facility by the Secretary of the Department of Veterans Affairs pursuant to 38 U.S.C. 7401–7408.

(5) If the individual practitioner is working at a health care facility operated by the Department of Veterans Affairs on a contractual basis pursuant to 38 U.S.C. 8153 and, in the performance of his duties, prescribes controlled substances, confirm that the individual practitioner meets the criteria for eligibility for appointment under 38 U.S.C. 7401–7408 and is prescribing controlled substances under the registration of such facility.

(b) An institutional practitioner that elects to conduct identity proofing must provide authorization to issue the authentication credentials to a separate entity within the institutional practitioner or to an outside credential Service provider or certification authority that meets the requirements of § 1311.105(a).

(c) When an institutional practitioner is conducting identity proofing and submitting information to a credential service provider or certification

authority to authorize the issuance of authentication credentials, the institutional practitioner must meet any requirements that the credential service provider or certification authority imposes on entities that serve as trusted agents.

(d) An institutional practitioner that elects to conduct identity proofing and authorize the issuance of the authentication credential as provided in paragraphs (a) through (c) of this section must do so in a manner consistent with the institutional practitioner's general obligation to maintain effective controls against diversion. Failure to meet this obligation may result in remedial action consistent with § 1301.36 of this chapter.

(e) An institutional practitioner that elects to conduct identity proofing must retain a record of the identity-proofing. An institutional practitioner that elects to issue the two-factor authentication credential must retain a record of the issuance of the credential.

§ 1311.115 Additional requirements for two-factor authentication.

(a) To sign a controlled substance prescription, the electronic prescription application must require the practitioner to authenticate to the application using an authentication protocol that uses two of the following three factors:

(1) Something only the practitioner knows, such as a password or response to a challenge question.

(2) Something the practitioner is, biometric data such as a fingerprint or iris scan.

(3) Something the practitioner has, a device (hard token) separate from the computer to which the practitioner is gaining access.

(b) If one factor is a hard token, it must be separate from the computer to which it is gaining access and must meet at least the criteria of FIPS 140–2 Security Level 1, as incorporated by reference in § 1311.08, for cryptographic modules or one-time-password devices.

(c) If one factor is a biometric, the biometric subsystem must comply with the requirements of § 1311.116.